

WHAT IS CLAIMED IS:

1. A capsule system for oral delivery of an active agent having low aqueous solubility, said 5 capsule system comprising:

an active retinoid agent having low aqueous solubility;

vehicle means for initially dissolving the active agent;

10 emulsifier means for promoting self-emulsification of the active agent and vehicle means in the gastrointestinal tract; and

15 capsule shell means for encapsulating the active agent, vehicle means, and emulsifier means, said capsule shell means being formulated to open upon ingestion into said gastrointestinal tract and release the active agent and vehicle means.

2. The capsule system according to claim 1 20 wherein said vehicle means comprises a liquid medium chain triglyceride fully dissolving said active retinoid agent.

3. The capsule system according to claim 2 25 wherein said liquid medium chain triglyceride comprises caprylic/capric triglyceride.

4. The capsule system according to claim 2 30 wherein said vehicle means is selected from a group consisting of: Ethyl oleate, Isopropyl myristate, Cetearyl octanoate, Corn oil, Cottonseed oil, Safflower oil, Olive oil, Peanut oil, Soybean oil, and Sesame oil.

35 5. The capsule system according to claim 3 wherein said emulsifier means comprises coemulsifiers.

6. The capsule system according to claim 5
wherein said coemulsifiers comprise Sorbitan Monooleate
and polysorbate 80.

5 7. The capsule system according to claim 5
wherein the coemulsifiers are selected from the group
consisting of: Sorbitan monooleate, Sorbitan
monolaurate, Sorbitan monopalmitate, Sorbitan
monostearate, Polysorbate 20, Polysorbate 40,
10 Polysorbate 60 and Polysorbate 80.

8. The capsule system according to claim 7
wherein said coemulsifiers are selected to match a
hydrophilic/lipophilic balance of the caprylic/capric
15 triglyceride.

9. The capsule system according to claim 8
wherein said active retinoid agent is tazarotene.

20 10. The capsule system according to claim 9
further comprising an antioxidant present in said
vehicle means.

11. The capsule system according to claim 10
25 wherein said capsule shell means further comprises an
opaque colorant.

12. The capsule system according to claim 11
wherein the Tazarotene is present in the amount of up
30 to about 34 mg/capsule, the antioxidant comprises
butylated hydroxyanisole in the amount of about 0.05%
w/w, the sorbitan monooleate is present in the amount
of about 5.0% w/w, the polysorbate 80 is present in the
amount of about 0.25% w/w and the caprylic/capric
35 triglyceride is present in the amount of about 94% w/w.

13. A capsule system for oral delivery of an active agent having low aqueous solubility, said capsule system comprising:

an active retinoid agent having low aqueous
5 solubility;

a liquid triglyceride fully dissolving said active agent;

emulsifier means for promoting self-emulsification of the liquid triglyceride and dissolved 10 active agent in a gastrointestinal tract; and

capsule shell means for encapsulating the liquid triglyceride with dissolved active agent and emulsifier means, said capsule shell means being formulated to open upon ingestion into said 15 gastrointestinal tract.

14. The capsule system according to claim 13 wherein said liquid triglyceride comprises caprylic/capric triglyceride.

20 15. The capsule system according to claim 14 wherein said liquid triglyceride comprises coemulsifiers.

25 16. The capsule system according to claim 15 wherein said coemulsifiers comprise Sorbitan Monooleate and polysorbate 80.

17. The capsule system according to claim 15 30 wherein said coemulsifiers are selected to match a hydrophilic/lipophilic balance of the caprylic/capric triglyceride.

18. The composition comprising the active agent 35 liquid triglyceride, coemulsifiers, and emulsifier means of claim 17.

19. The capsule system according to claim 17 wherein said active retinoid agent is Tazarotene.

20. The capsule system according to claim 19 further comprising an antioxidant present in said vehicle means.

21. The capsule system according to claim 20 wherein said capsule shell means further comprises an opaque colorant.

22. The capsule system according to claim 21 wherein the Tazarotene is present in the amount of between about 0.1 mg/capsule and about 34 mg/capsule, the antioxidant comprises butylated hydroxyanisole in the amount of about 0.05% w/w, the sorbitan monooleate is present in the amount of about 5.0% w/w capsule, the polysorbate 80 is present in the amount of about 0.25% w/w and the caprylic/capric triglyceride is present in the amount of about 94% w/w.

23. The composition comprising the Tazarotene, butylated hydroxyanisole, sorbitan monooleate, polysorbate 80 and caprylic/capric triglyceride of claim 22.

24. A method for enabling delivery of an active agent having low aqueous solubility, the method comprising the steps of:

30 providing an active retinoid agent having low aqueous solubility;

dissolving the active agent in a vehicle in order to eliminate initial active agent dissolution within a gastrointestinal tract;

35 incorporating an emulsifier into the vehicle in order to promote self-emulsification of the active agent and vehicle in the gastrointestinal tract; and

encapsulating the active agent, vehicle and emulsifier with a capsule shell formulated to open upon ingestion into said gastrointestinal tract.

5 25. The method according to claim 24 wherein the step of providing an active retinoid agent comprises providing tazarotene.

10 26. The method according to claim 25 further comprising the step of incorporating an antioxidant into the vehicle.

15 27. The method according to claim 26 further comprising the step of incorporating an opaque colorant into the capsule shell.

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